MAR 1 0 2014

Section 5: 510 (k) Summary

(As required by 21 CFR 807.92 and 21 CFR 807.93)

Submitter Information	
Name	DePuy Orthopaedics
Address	700 Orthopaedic Drive Warsaw, IN 46582
Phone number	574-372-7745
Fax number	574- 371-4987
Establishment Registration Number	1818910
Name of contact person	Megan Burns
Date prepared	February 14, 2014
Name of device	
Trade or proprietary name	**DePuy Pinnacle ALTRX Acetabular Liners**
Common or usual name	Polyethylene Acetabular Cup Liner
Classification name	Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented
Class	II
Classification panel	Orthopedics
Regulation	21 CFR 888.3358: Hip joint metal/polymer/metal, semi-constrained, porous-coated, uncemented prosthesis 21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis
Product Code(s)	LPH, LZO
Legally marketed device(s) to which equivalence is claimed	DePuy Pinnacle ALTRX Acetabular Liners (K102423, cleared October 29, 2010)
Reason for 510(k) submission	Line extension
Device description	The DePuy Pinnacle ALTRX Acetabular Liners are part of a modular system designed to replace the natural articular surface of the hip joint in total hip replacement. The liner is manufactured from ultra high molecular weight polyethylene (UHMWPE), which locks into a porous coated, hemispherical outer shell component manufactured from titanium alloy (Ti-6Al-4V). The liner component articulates with a metal or ceramic femoral head of an appropriate diameter. The subject devices represent additional sizes and style combinations of the predicate acetabular liners.

Intended use of the device	The subject liners are intended to be used with the DePuy Pinnacle metal acetabular shells and DePuy metal or ceramic femoral heads to resurface the acetabular socket in cementless total hip arthroplasty. Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to support the components.
Indications for use	The DePuy Pinnacle ALTRX Acetabular Cup Liners are indicated for use in total hip replacement procedures. Total hip replacement is indicated in the following conditions: 1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia. 2. Avascular necrosis of the femoral head. 3. Acute traumatic fracture of the femoral head or neck. 4. Failed previous hip surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement. 5. Certain cases of ankylosis. The Pinnacle ALTRX Acetabular Cup Liners are indicated for use with Pinnacle Acetabular Cups in cementless applications.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE			
Characteristics	**Subject Device: DePuy Pinnacle ALTRX Acetabular Liners**	**Predicate Device: DePuy Pinnacle ALTRX Acetabular Liners (K102423 and K072963)**	**Reference Device: DePuy Pinnacle Marathon Acetabular Liners (K033273 and (K033338)**
Intended Use	Total Hip Arthroplasty	Same	Same
Material	UHMWPE, GUR 1020	Same	UHMWPE, GUR 1050
Fixation	Uncemented	Same	Same
Compatible Acetabular Shell Diameters	52-76 mm	44-76 mm	38-76mm
Compatible Femoral Head Diameters	28, 32, 36, and 40 mm	28, 32, 36, 40, 44, and 48 mm	22, 28, 32, 36, 40, 44, and 48 mm
Minimum cross-sectional thickness	3.05 mm	3.14 mm	3.25 mm
Sterile Method	Gas Plasma	Same	Same
Packaging	Double PETG blister with Tyvek peel lid	Same	Same
Shelf Life	5 years	Same	Same

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Non-clinical testing, including Impingement, High Angle Fatigue, Push-out and Torque-out testing demonstrated that the subject devices met the applicable performance requirements and are as safe and effective as a legally marketed device. Therefore, the subject device is substantially equivalent to the predicate device.

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

No clinical tests were conducted to demonstrate substantial equivalence.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The subject DePuy ALTRX Acetabular Liners are substantially equivalent to the predicate DePuy ALTRX Acetabular Liners.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 10, 2014

DePuy Orthopaedics, Inc
Ms. Megan Burns
Senior Associate, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K132959
Trade/Device Name: DePuy Pinnacle AltrX Acetabular Liners
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO
Dated: December 19, 2013
Received: December 20, 2013

Dear Ms. Burns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510 (k) Number (if known): K132959

Device Name: DePuy Pinnacle AltrX Acetabular Liners

Indications for Use:

The DePuy Pinnacle AltrX Acetabular Cup Liners are indicated for use in total hip replacement procedures.

Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The Pinnacle AltrX Acetabular Cup Liners are indicated for use with Pinnacle Acetabular Cups in cementless applications.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Concurrence of Center for Devices and Radiological Health (CDRH)

Elizabeth L. Frank -S

(Division Sign-Off
Division of Orthopedic Devices
510(k) Number: K132959